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*Stephen B. Latzer*  
 Stephen B. Latzer

Regarding the following Application:

Applicant(S): STEINER, Mitchell S. Examiner: FUBARA, BLESSING M  
 et al.

Serial No./ 10/747,685 Group Art Unit: 1618  
 Patent No.:

Filed/Issued Date: December 30, 2003 Attorney Docket No.: P-2769-US10

Title: A METHOD FOR CHEMOPREVENTION OF PROSTATE CANCER

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| 1. <input type="checkbox"/> Provisional Cover Sheet   | 9. <input type="checkbox"/> Response to Notice to File Missing Parts  |
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| 5. <input type="checkbox"/> Patent Application Under 35 USC 111(a)  | 13. <input type="checkbox"/> Preliminary Amendment  |
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Attorney Docket No.: P-2769-US10

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): STEINER, Mitchell S. et al. Examiner: FUBARA, BLESSING M

Serial No.: 10/747,685 Group Art Unit: 1618

Filed: December 30, 2003

Title: A METHOD FOR CHEMOPREVENTION OF PROSTATE CANCER

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## INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§1.56, 1.97 and 1.98, this Information Disclosure Statement includes Form PTO/SB/08:

1. ☒ listing documents including patents, publications and other information for consideration by the Examiner, however, since the subject application was filed after June 30, 2003, copies of United States patents and/or United States patent application publications are not included in this information disclosure statement; and/or
2. ☒ listing documents including patents, publications and other information that have been previously cited or submitted to the Patent Office in prior application U.S. Serial No. 10/611,056, filed November 8, 2000, which is properly identified and relied on for an earlier effective filing date under 35 U.S.C. 120 for consideration by the Examiner; however, in accordance with 37 C.F.R. 1.98(d), copies of such documents are not included in this information disclosure statement; and/or
3. ☐ listing documents including patents, publications, and other information for consideration by the Examiner, copies of which are included with this information disclosure statement;
4. ☐ listing other information for the Examiner's consideration which was cited in a communication from a foreign patent office in a counterpart foreign application, a copy of which is included with this information disclosure statement.

APPLICANTS: STEINER, Mitchell S., et al  
SERIAL NO.: 10/747,685  
FILED: December 30, 2003  
Page 2

The information herein cited is only in fulfillment of Applicant(s) duty of candor in disclosing all information brought to Applicant(s) attention. This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art". If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicant(s) reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant(s) further reserve(s) the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each and every document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application and is evidence that the Examiner has considered the document.

This Information Disclosure Statement is being filed:

I) ☐ Within three (3) months of filing the subject Application or entry of the subject Application into the national stage or before mailing of the first Office Action on the merits of the subject Application or a request for continued examination thereof, whichever event occurs last pursuant to of 37 C.F.R. §1.97 (b); or

II) ☒ After the period specified in (I) but before the mailing date of either a final Official Action under 37 C.F.R. §1.113 or a notice of allowance under 37 C.F.R. §1.311 whichever occurs first and;

1. ☐ the undersigned hereby states that each item of information listed on the Form PTO-1449 was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement or (ii) not cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, not known to any individual designated in §1.56(c) more than three (3) months prior to the filing of this information disclosure statement; or

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APPLICANTS:  
SERIAL NO.:  
FILED:  
Page 3STEINER, Mitchell S., et al  
10/747,685  
December 30, 2003

2. ☒ the undersigned hereby authorizes the Patent Office to charge the fee in the amount of \$180.00 under 37 C.F.R. §1.17 (p) to Deposit Account 50-3355.

III) ☐ After the period in (I) and (II) but before the payment of the issue fee and,

1. The undersigned hereby states:

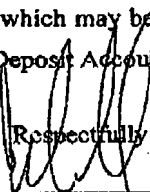
a) ☐ that each item of information cited on the form PTO-1449 was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement; or

b) ☐ that no items of information contained in Form PTO-1449 was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; and

2. ☐ The undersigned hereby authorizes the Patent Office to charge the Petition fee in the Amount of \$180.00 under 37 C.F.R. §1.17 (p) to Deposit Account 50-3355.

Except for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-3355.

Respectfully submitted,

  
Mark S. Cohen  
Attorney/Agent for Applicant(s)  
Registration No. 42,425

Dated: August 7, 2007

Pearl Cohen Zedek Latzer, LLP  
1500 Broadway, 12th Floor  
New York, New York 10036  
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Fax: (646) 878-0801

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Substitute for form 1449A/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/747,685
		Filing Date	December 30, 2003
		First Named Inventor	STEINER, Mitchell S.
		Group Art Unit	1614
		Examiner Name	Not yet known
Sheet	1	of	10
		Attorney Docket Number	P-2769-US10

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cito. No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
	A	4,990,538		Harris et al.	February 5, 91
	B	5,788,964		Beral et al.	August 4, 98
	C	5,650,425		Diegaon et al.	July 22, 97
	D	4,696,949		Toivola et al.	Sept 29, 87
	E	5,491,173		Toivola et al.	Feb. 13, 1996
	F	5,571,534		Jalonen et al.	Nov. 5, 1996
	G	5,605,700		DeGregorio et al.	Feb. 25, 1997
	H	5,595,722		Grainger et al.	Jan. 21, 1997
	I	5,599,844		Grainger et al.	Feb. 4, 1997
	J	5,629,007		Audia et al.	May 13, 1997
	K	5,635,197		Audia et al.	June 3, 1997
	L	5,595,985		Lubrie	Jan. 21, 1997
	M	5,441,986		Thompson, et al	August 15, 1995
	N	5,859,045		Treppendahl, et al	January 12, 1999
	O	5,935,987		Treppendahl, et al	August 10, 1999
	P	6,899,888		Steiner, et al	05-2005
	Q	2006/0019989		Steiner, et al	01-2006
	R	2005/0171073		Steiner, et al	08-2005
	S	2004/0186185		Steiner, et al	09-2004
	T	2005/0080143		Steiner, et al	04-2005
	U	2006/0270641		Steiner, et al	11-2006
	V	2004/0176470		Steiner, et al	09-2004
	W	2004/0096510		Steiner, et al	05-2004
	X	2003/0153625		Steiner, et al	08-2003

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		Application Number	10747,685		
		Filing Date	December 30, 2003		
		First Named Inventor	STEINER, Mitchell S.		
		Group Art Unit	1614		
		Examiner Name	Not yet known		
Sheet	2	of	10	Attorney Docket Number	P-2769-US10

FOREIGN PATENT DOCUMENTS							
Examiner Initials <sup>a</sup>	Cite No.	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>b</sup>
		Office <sup>3</sup>	Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	Y	WO	98/58634	Degregorio, et al	December 30, 1998		<input type="checkbox"/>
	Z	EP	415 623 A2	Harris et al	March 6, 1991		<input type="checkbox"/>
	AA	EP	616 529 B1	Jalonen, et al	September 28, 1994		<input type="checkbox"/>
	AB	EPC	095875	Toivola, et al	Dec 7, 1995		<input type="checkbox"/>
	AC	WO	95/26720	Bieganski et al	Oct 12, 1995		<input type="checkbox"/>
	AD	WO	0008001	Huehner, et al	Feb 17, 2000		<input type="checkbox"/>
	AE	WO	95/26720	Bieganski, et al	October 12, 1995		<input type="checkbox"/>
	AF	WO	00/19998	KGK SYNERGIZE	April 13, 2000		<input type="checkbox"/>
	AG	WO	97/25038	NOVO NORDISK	July 17, 1997		<input type="checkbox"/>
	AJ	WO	99/08682	DUKE UNIVERSITY	February 25, 1999		<input type="checkbox"/>
	AI	WO	97/25037	NOVO NORDISK	July 17, 1997		<input type="checkbox"/>

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			Application Number	10747,685	
			Filing Date	December 30, 2003	
			First Named Inventor	STEINER, Mitchell S.	
			Group Art Unit	1614	
			Examiner Name	Not yet known	
			Attorney Docket Number	P-2769-US10	
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U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document Number Kind Code <sup>2</sup> (if known)		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AJ	4,329,364		Neri et al.	May 11, 1982	
	AK	4,474,813		Neri et al.	Oct. 2, 1984	
	AL	6,080,877		Swindell et al	June, 2000	
	AM	6,265,448		Steiner et al	July 24, 2001	
	AN	6,410,043		Steiner et al	June 25, 2002	
	AO	6,632,447		Steiner et al	Oct 14, 2003	
	AP	6,413,533		Steiner et al	July 2, 2002	
	AQ	6,413,534		Steiner et al	July 2, 2002	
	AR	6,413,535		Steiner et al	July 2, 2002	
	AS	4,996,225		Toivola et al	Feb 26, 1991	
	AT	5,811,120		Gibson et al	Sept 22, 1998	
	AU	5,972,383		Gibson et al	Oct 26, 1999	
	AV	4,418,068		Jones	Nov 29, 1983	
	AW	5,852,059		Thompson, et al	December 22, 1998	
	AX	5,827,892		Loeser, et al	October 27, 1998	
	AY	5,821,254		Sporn, et al	October 13, 1998	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	AZ	WO	94/12162		Warri et al	June 9, 1994		<input type="checkbox"/>
	RA	WO	99/56739		Steiner et al	November 11, 1999		<input type="checkbox"/>
	BB	WO	00/47214		Healey et al	August 17, 2000		<input type="checkbox"/>
	BC	WO	96/09046		Audia et al	March 28, 1996		<input type="checkbox"/>
	BD	EP	0 670 162		Gibson et al	Sept 6, 1995		<input type="checkbox"/>

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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/747,885
		Filing Date	December 30, 2003
		First Named Inventor	STEINER, Mitchell S.
		Group Art Unit	1814
		Examiner Name	Not yet known
		Attorney Docket Number	P-2768-US10
Sheet	4 of 10		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	BT	Greenwald "Expanding Horizons in Breast and Prostate Cancer Prevention and Early Detection", in J. Cancer Education, 1993, Vol. 8, No. 2, pages 91-107.	<input type="checkbox"/>
	BF	Brawley et al., "Chemoprevention of Prostate Cancer" in Urology, 1994, Vol. 43, No. 5.	<input type="checkbox"/>
	BC	Kelloff et al., "Introductory Remarks: Development of Chemopreventive Agents for Prostate Cancer" in Journal of Cellular Biochemistry, 1992, Supplement 16H: 1-8.	<input type="checkbox"/>
	BH	Lucia et al., "Chemopreventive Activity of Tamoxifen, N-(4-Hydroxyphenyl)retinamide, and the Vitamin D Analogue Ro24-553 1 for Androgen-promoted Carcinomas of the Rat Seminal Vesicle and Prostate" in Cancer Research, 1995, vol. 55, pages 5621-5627.	<input type="checkbox"/>
	BI	Potter et al., "A Mechanistic Hypothesis for DNA Adduct Formation By Tamoxifen Following Hepatic Oxidative Metabolism" in Carcinogenesis, 1994, Vol. 15, No. 3, pages 439-442.	<input type="checkbox"/>
	BJ	Schneider Martin R. et al. "Nonsteroidal Antiestrogens and Partial Estrogens with Prostatic Tumor Inhibiting Activity", Cancer Research Clinical Oncology Springer-Verlag 1986, J Cancer Res Clin Oncol (1986) 112: 258-265, p. 258-265.	<input type="checkbox"/>
	BK	Martel Celine et al. "Binding Characteristics of Novel Nonsteroidal Antiestrogens to the Rat Uterine Estrogen Receptors", Pergamon, J. Steroid Biochem. Molcc. Bio. Vol 64, No. 3-4, pp. 199-205, 1998.	<input type="checkbox"/>
	BL	Valavaara Ritva, MD, PhD "Reliability of Estrogen Receptors in Predicting Response To Antiestrogens", Oncology, Volume 11 Number 5 Supplement No. 4 p. 14-18.	<input type="checkbox"/>
	BM	Richard Gams, MD "Phase III Trials of Toremifene vs Tamoxifen" Oncology Volume 11, Number 5, Supplement 4, May 1997	<input type="checkbox"/>
	BN	Christian Rohlf et al. "Prostate Cancer Cell Growth Inhibition by Tamoxifen Is Associated With Inhibition of Protein Kinase C and Induction of p21" The Prostate 37:51-59 (1998) ©1998 Wiley-Liss, Inc	<input type="checkbox"/>
	BO	Nevalanne et al. "Hormone Regulation of Human Prostate in Organ Culture" Cancer Res, vol. 53, no. 21, 1993, pages 5199-5207, X0002117653.	<input type="checkbox"/>
	BP	Gingrich et al., "Androgen-independent Prostate Cancer Progression in the TRAMP Model", in Cancer Research 57, November 1, 1997, pages 4687-4691.	
	BQ	Gingrich et al., "Pathologic Progression of Autochthonous Prostate Cancer in the TRAMP Model", Prostate Cancer and Prostatic Diseases, 1999, 2, Pages 70-75.	
	BR	Gingrich et al., "Metastatic Prostate Cancer in a Transgenic Mouse", in Cancer Research 56, September 15, 1996, pages 4096-4102.	
	BS	Gershunovich et al., "A Phase III Comparison of Two Toremifene Doses to Tamoxifen in Postmenopausal Women with Advanced Breast Cancer", Breast Cancer Research and Treatment 45, 1997, Pages 251-262.	

Examiner Signature	Date Considered
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\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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		<b>First Named Inventor</b>	<b>STEINER, Mitchell S.</b>
		<b>Group Art Unit</b>	<b>1614</b>
		<b>Examiner Name</b>	<b>Not yet known</b>
(use as many sheets as necessary)		<b>Attorney Docket Number</b>	<b>P-2769-US10</b>
<b>Sheet</b>	<b>5</b>	<b>of</b>	<b>10</b>

<b>NON PATENT LITERATURE DOCUMENTS</b>			
<b>Examiner Initials*</b>	<b>Cite No.<sup>1</sup></b>	<b>Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.</b>	<b>T<sup>2</sup></b>
	BT	Hayes et al. "Randomized Comparison of Tamoxifen and Two Separate Doses of Toremifene in Postmenopausal Patients with Metastatic Breast Cancer", Journal of Clinical Oncology, Vol. 13, No. 10, 1995, pages 2556-2566.	
	BU	Pyrhonen et al., "Comparison of Toremifene and Tamoxifen in Postmenopausal Patients with Advanced Breast Cancer: a Randomized Double-blind, the 'Nordic' Phase III Study", British Journal of Cancer, 1997, 76(2), pages 270-277.	
	BV	Neubauer et al., "Endocrine and Antiproliferative Effects of Raloxifene (LY156758) in the Male Rat", The Prostate 23, 1993, pages 245-262.	
	BW	Pollard, "Prevention of Prostate-Related Cancers in Lobund-Wistar Rats", The Prostate 39, 1999, pages 305-309.	
	BX	Simard et al., "Roxifene Shows Pure Antiestrogenic Activity in Pituitary Gonadotrophs", Molecular and Cellular Endocrinology 39, 1985, pages 141-144.	
	BY	Perry "High Dose Toremifene for Estrogen and Progesterone Receptor Negative Metastatic Breast Cancer: a Phase II Trial of the Cancer and Leukemia Group B (CALGB)", in Breast Cancer Res Treat - 1995; 26(1): 25-40	
	BZ	Hietanen T "Open Phase II Study of High-Dose Toremifene as First-Line Therapy for Advanced Breast Cancer" in Oncology - May 1997; 11(5 Suppl 4): 37-40.	
	CA	Black et al. "Uterine Bioassay of Tamoxifen, Trioxifen and a New Estrogen Antagonist (LY117018) in Rats and Mice" in Life Sciences, 1980, Vol. 26, pp. 1453-1458	
	CB	Moore et al. "Regulation of Cytoplasmic Dihydrotestosterone Binding in Dog Prostate by 17 $\beta$ -Estradiol", in J. Clin. Invest. © The American Society for Clinical Investigation, Inc., Vol. 63 March 1979, pages 351-357.	
	CC	Shirai et al. "Effects of Testosterone, Dihydrotestosterone and Estrogen on 3,2'-Dimethyl-4-Aminobiphenyl-Induced Rat Prostate Carcinogenesis" in Int. J Cancer: 57, 224-228 (1994)	
	CD	Greenwald et al. "Breast Cancer Prevention and Early Detection", pages 93-106.	
	CE	Shenfeld et al. "Androgen Deprivation Therapy", Chapter 37, Section III/Prostate Cancer, pages 467-477	
	CF	Jordan VC "Toremifene As An Anticancer Agent", Cancer Invest 1990; 8(2) 271	
	CG	Karlsson S. et al. "A Two-Year Dietary Carcinogenicity Study Of The Antiestrogen Toremifene In Sprague-Dawley Rats" Drug Chem Toxicol 1996 Nov; 19(4): 245-66.	
	CH	Powles TJ "Status Of Antiestrogen Breast Cancer Prevention Trials" Oncology (Huntingt) 1998 Mar; 12(3 Suppl 5): 28-31.	
	CI	Moon RC et al. "Chemoprevention of MNU-Induced Mammary Tumorigenesis by Hormone Response Modifiers: Toremifene, RU 16117, Tamoxifen, Aminoglutethimide and Progesterone", Anticancer Res 1994 May-June; 14(3A): 889-93.	

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10747,685
		Filing Date	December 30, 2003
		First Named Inventor	STEINER, Mitchell S.
		Group Art Unit	1614
		Examiner Name	Not yet known
Sheet 6 of 10	Attorney Docket Number	P-2769-US10	

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	CJ	Nevalainen MT et al. "Expression and Hormone Regulation Of Prolactin Receptors In Rat Dorsal and Lateral Prostate", <i>Endocrinology</i> 1996 Jul; 137(7): 3078-88.	
	CK	Fockens JA et al. "Expression Of Prostate-Specific Antigen (PSA) Correlates With Poor Response To Tamoxifen Therapy In Recurrent Breast Cancer", <i>Br J Cancer</i> 1999 Feb; 79(5-6): 888-94.	
	CI	Brandes LJ et al. "Salutary Clinical Response Of Prostate Cancer To Antiandrogen Withdrawal: Assessment Of Flutamide In An In Vitro Paradigm Predictive Of Tumor Growth Enhancement", <i>Clin Cancer Res</i> 1997 Aug; 3(8): 1357-61.	
	CM	Miyata E et al. "Effects Of Tamoxifen, An Antiestrogen, On Rat Prostate Carcinogenesis by 3,2'-Dimethyl-4-Aminobiphenyl And Testosterone Do Not Support An Estrogen Role In Testosterone Promotion", <i>Prostate</i> 1997 Apr 1; 31(1):9-13.	
	CN	Pienta KJ et al. "A Phase II Evaluation Of Oral Tamoxifen And Intermittent Intravenous Vinblastine In Hormone-Refractory Adenocarcinoma Of The Prostate", <i>Am J Clin Oncol</i> 1996 Oct; 19(5):500-3.	
	CO	Pienta KJ et al. "Inhibition Of Prostate Cancer Growth By Vinblastine And Tamoxifen", <i>Prostate</i> 1995 May; 26(5): 270-4.	
	CP	Lippman SM et al. "Cancer Chemoprevention", <i>J Clin Oncol</i> 1994 Apr; 12(4):851-73.	
	CQ	Szarka CF et al. "Chemoprevention Of Cancer", <i>Curr Probl Cancer</i> 1994 Jan-Feb; 18(1):6-79.	
	CR	Bergan RC et al. "A Phase II Study Of High-Dose Tamoxifen In Patients With Hormone-Refractory Prostate Cancer", <i>Clin Cancer Res</i> 1999 Sep; 5(9): 2366-73.	
	CS	Chang William Y et al. "Estrogen Receptor-? : Implications For The Prostate Gland" <i>The Prostate</i> 40:115-124 (1999)	
	CT	Shughrue Paul J. et al. "Comparative Distribution Of Estrogen Receptor-? (Er-?) And ? (Er-?) mRNA In The Rat Pituitary, Gonad, And Reproductive Tract" <i>Steroids</i> 63: 498-504, 1998, Elsevier Science Inc.	
	CU	Prins Gail S. et al. "Neonatal Estrogen Exposure Up-Regulates Estrogen Receptor Expression In The Developing And Adult Rat Prostate Lobes*", <i>Endocrinology</i> 138: 1801-1809, 1997	
	CV	Hempstock J. et al. "Growth Inhibition Of Prostate Cell Lines In Vitro By Phyto-Oestrogens", <i>British Journal Of Urology</i> (1998). 82. 560-563.	
	CW	Awoniyi Caleb A. et al. "Neonatal Exposure To Coumestrol, A Phytocytrogen, Does Not Alter Spermatogenic Potential In Rats", <i>Endocrine</i> , vol. 7, no. 3, 337-341, December 1997.	
	CX	"Chemoprevention Of Prostate Cancer: Guidelines For Possible Intervention Strategies", <i>Journal of Cellular Biochemistry, Supplement</i> 16H:140-145 (1992).	

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Application Number</b>	10/747,685
		<b>Filing Date</b>	December 30, 2003
		<b>First Named Inventor</b>	STEINER, Mitchell S.
		<b>Group Art Unit</b>	1614
		<b>Examiner Name</b>	Not yet known
		<b>Attorney Docket Number</b>	P-2769-US10
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	CY	"When Is Intervention Warranted?", Journal Of Cellular Biochemistry, Supplement 161:138-139 (1992).	
	CZ	"Editorial: A New Actor In The Estrogen Receptor Drama-Entre ER-?", Endocrinology Vol. 138, No. 3, (1997).	
	DA	Kuiper George G. J. M. et al. "Comparison Of The Ligand Binding Specificity And Transcript Tissue Distribution Of Estrogen Receptors 1 and 2", Endocrinology Vol. 138, No. 3, 863-870 (1997).	
	DB	Colletta Anthony A. et al. "Alternative Mechanisms Of Action Of Anti-Oestrogens" Breast Cancer Research and Treatment 31: 5-9, 1994.	
	DC	Griffiths K. et al. "Further Insights Into Endocrine Disease - Diet and Prostate Disease" An IPHC Teaching Programme.	
	DD	Yu H et al. "Induction Of Prostate Specific Antigen Production By Steroids And Tamoxifen In Breast Cancer Cell Lines", Breast Cancer Res Treat 1994; 32(3):291-300.	
	DE	Horton J et al. "Tamoxifen In Advanced Prostate Cancer: An ECOG Pilot Study", Prostate 1988; 12(2):173-7.	
	DF	Kangas L. "Development And Biochemical Pharmacology Of Toremifene, An Antiestrogenic Antitumor Drug", Acta Obstet Gynecol Scand 1991; 70(4-5): 399.	
	DG	Anttila M et al. "Pharmacokinetics Of The Novel Antiestrogenic Agent Toremifene In Subjects With Altered Liver And Kidney Function" Clin Pharmacol Ther 1995 Jun; 57(6):628-35.	
	DH	Kamat AM et al. "Chemoprevention Of Urological Cancer", The Journal Of Urology, Vol. 161, 1748-1760, June 1999, p. 1748-1760.	
	DI	Fleton SA "Potential New Antiestrogens For The Treatment Of Breast Cancer", Highlights in Oncology Practice Vol. 15, No. 2, 1997 p. 47-52	
	DJ	Nevalainen M.T. et al. "Estrogen and Prolactin Regulation of Rat Dorsal and Lateral Prostate in Organ Culture", Endocrinology, Vol. 129, No. 2 pages 612-618	
	DK	Moxn R.C. et al. "Chemoprevention of MNU-Induced Mammary Tumorigenesis by Hormone Response Modifiers: Toremifene, RU 16117, Tamoxifen, Aminoglutethimide and Progesterone", Anticancer Research 14: 889-894 (1994)	
	DL	Price K. R. et al. "Naturally Occurring Oestrogens in Food - A review", Food Additives and Contaminants, 1985, Vol. 2, No. 2, 73-106.	

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		Application Number	10/747,685
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Filing Date	December 30, 2003
		First Named Inventor	STEINER, Mitchell S.
		Group Art Unit	1614
		Examiner Name	Not yet known
		Attorney Docket Number	P-2769-US10
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Sheet	8	of	10

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	DM	Cheng F. et al. "Endocrinology Of The Prostate", Prostate Discases, chapter 5- p. 57-71.	
	DN	Bonkhoff H et al. "Estrogen Receptor Expression In Prostate Cancer and Premalignant Prostatic Lesions", American Journal of Pathology, Vol. 155, No. 2 August 1999.	
	DX	"New Research Approaches In The Prevention And Cure Of Prostate Cancer", American Association For Cancer Research. December 1998	
	DP	Xiaolin Zi et al. "Silibinin Decreases Prostate-Specific Antigen With Cell Growth Inhibition Via G1 Arrest, Leading To Differentiation Of Prostate Carcinoma Cells: Implications For Prostate Cancer Intervention", Proc. Natl. Acad. Sci. USA Vol. 96, pp. 7490-7495, June 1999. Medical Sciences.	
	DQ	Landstrom M, et al. "Inhibitory Effects Of Soy and Rye Diets On The Development Of Dunning R3327 Prostate Adenocarcinoma in Rats, The Prostate 36: 151-161 (1998).	
	DR	Buckle-Sam J. et al. "The Selective Estrogen Receptor Modulator, Raloxifene: An Overview Of NonClinical Pharmacology And Reproductive And Developmental Testing", Reprod Toxicol 1998 May-June; 12(3):217-21.	
	DS	Treinen KA et al. "An Evaluation Of The Novel Selective Estrogen Receptor Modulator, Idoxifene, For Effects On Reproduction In Rats And Rabbits, Toxicol Sci 1998 Feb; 41(2):199-207.	
	DT	Boehm S et al. "Estrogen Suppression As A Pharmacotherapeutic Strategy In The Medical Treatment Of Benign Prostatic Hyperplasia: Evidence For Its Efficacy From Studies With Mepartricin" Wien Klin Wochenschr 1998 Dec 11; 110(23):817-23.	
	DU	Dhar JD et al. "Estrogen, Androgen and Antiestrogen Responses In The Accessory Organs Of Male Rats During Different Phases Of Life", Endocr Res 1998 May; 24(2): 159-69.	
	DV	West Neal B et al. "Estrogen and Progesterone Receptors And Aromatase Activity In Rhesus Monkey Prostate" Endocrinology, Vol. L. 123, (1998)	
	DW	Strauss L "Genistein Exerts Estrogen-Like Effects In Male Mouse Reproductive Tract", Molecular and Cellular Endocrinology 144 (1998) 83-93, Elsevier Science Ireland Ltd.	

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	DX	Hobisch Alfred "Metastatic Lesions From Prostate Cancer Do Not Express Oestrogen And Progesterone Receptors" J. Pathol. 182: 356-361, 1997.	
	DZ	Albert David S. et al. "An Overview Of Clinical Cancer Chemoprevention Studies With Emphasis On Positive Phase III Studies" Overview of Diet Cancer 6928-6975 (1995)	
	EA	Strom Sara S. et al. "Phytoestrogen Intake and Prostate Cancer: A Case-Control Study Using A New Database", Nutrition and Cancer, 33(1), 20-25. (1999).	
	EB	Kelloff GJ et al. "Strategies For Chemoprevention Of Prostate Cancer", Prostate Cancer and Prostate Disease (1988) 5: 107.	
	EC	Duelke-Sam Judy et al. "The Selective Estrogen Receptor Modulator, Raloxifene: An Overview Of NonClinical Pharmacology and Reproductive Development Testing", Reproductive Toxicology Vol. 12, No. 3 pp. 217-221, 1998.	
	ED	Prins Gail S. "Developmental Estrogenization Of The Prostate Gland", Prostate: Basic and Clinical Aspects p. 245-263 (1997).	
	EF	Kuiper George G. J. M. "Cloning Of A Novel Estrogen Receptor Expressed In Rat Prostate And Ovary", Proc. Natl. Acad. Sci USA Vol. 93, pp. 5925-5930, June 1996 Biochemistry.	
	EG	Kuiper George G. J. M. "Interaction Of Estrogenic Chemicals and Phytoestrogens With Estrogen Receptor ?", Endocrinology Vol. 139, No. 10 (1998).	
	EH	Horton John et al. "Tamoxifen In Advanced Prostate Cancer" An ECOG Pilot Study", The Prostate 12: 173-177 (1988).	
	EI	Hayes "A Randomized Comparison Of Tamoxifen, Trioxifene And A New Estrogen Antagonist (LY117018) In Rats And Mice" In Life Sciences, 1980, vol. 26, pp. 1453-1458.	
	EJ	Jordan Craig V. "Antiestrogenic Action of Raloxifene and Tamoxifen: Today and Tomorrow" Journal of National Cancer Institute, Vol. 90, No. 13, July 1, 1998	
	EK	Warri Anni. M. et al "Apoptosis In Torcemifene Induced Growth Inhibition of Human Breast Cancer Cells in Vivo and In Vitro" Journal of National Cancer Institute, Vol. 85, No. 17, September 1, 1993	
	EL	Mohbs, B.G. et al "Concentration and Cellular Distribution of Androgen Receptor in Human Prostatic Neoplasia: Can Estrogen Treatment Increase Androgen Receptor Content?" J. Steroid Biochem. Vol. 19, No. 3 pp. 1279-1290, 1983.	

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		<b>First Named Inventor</b>	<b>STEINER, Mitchell S.</b>
		<b>Group Art Unit</b>	<b>1614</b>
		<b>Examiner Name</b>	<b>Not yet known</b>
<b>Sheet</b>	<b>10</b>	<b>of</b>	<b>10</b>
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	EM	Krieg, Michael et al "Androgens and Estrogens: Their Interaction with Stroma and Epithelium of Human Benign Prostatic Hyperplasia and Normal Prostate" J. Steroid Biochem. Vol. 19, No. 1 pp. 155-161, 1983	
	EN	Hard, Gordon C. et al. "Major Difference in the Hepatocarcinogenicity and DNA Adduct Forming Ability between Toremifene and Tamoxifen in Female Crl: CD(BR) Rats" Cancer Research 53, 4534-4541, October 1, 1993	
	EO	Boyle Peter et al "Epidemiology of Prostate Cancer Chemoprevention" Eur Urol 1999; 35:370-376	
	EP	Bostwick, David G. et al "Reversibility of Prostatic Intraepithelial Neoplasia: Implications for Chemoprevention" Eur. Urol 1999; 35:492-495	
	EQ	Bostwick David "Prospective Origins of Prostate Carcinoma" American Cancer Society 1996	
	ER	The Lancet "The Challenge of Breast Cancer" Vol. 342, September 18, 1993	
	ES	Zaridze, David G. et al "International Trends in Prostatic Cancer" Int. J. Cancer: 33, 223-230 (1984)	
	ET	Nevalainen MT et al "Hormone regulation of human prostate in organ culture" Cancer Res. 1993 Nov 1;53(21):5199-207	
	EU	Steiner, et al "Selective Estrogen Receptor Modulators for the Chemoprevention of Prostate Cancer." Urology 2001 57 (4 Suppl. 1) 68-72	
	EV	Raghow, et al "Toremifene prevents prostate cancer in the transgenic adenocarcinoma of mouse prostate model." Cancer Res. 2002 1;62(5): 1370-1376	
	EW	Steiner, et al "Antiestrogens and selective estrogen receptor modulators reduce prostate cancer risk" World J. Urol. 2003 21 (1):31-6	
	EX	Neubauer, et al "Raloxifene (LY156758) produces antimetastatic responses and extends survival in the PAII rat prostatic adenocarcinoma model." Prostate 1995 27(4):220-9.	
	EY	Pylkkanen, et al "Animal models for the precancerous lesions of the prostate." Eur Urology 1996;30(2):243-8	
	EZ	Schneider, et al "Nonsteroidal antiestrogens and partial estrogens with prostatic tumor inhibiting activity." J. Cancer Res. Clin. Oncol. 1986; 112(3):258-65.	
	FA	Schneider, et al "Effect of zindoxifene on experimental prostatic tumors of the rat. J Cancer Res. CLIn. Oncol. 1991;117(1) 33-6	
	FB	Ip, et al "Functionality of estrogen receptor and tamoxifen treatment of R3327 Dunning rat prostate adenocarcinoma." Cancer Res 1980 40(7) 2188-93	

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